

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY
COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS

CHECKLIST FOR RESEARCH INVOLVING NEONATES

Principal Investigator (please print):

Project Title:

1. Is the neonate viable?

If yes, use the checklist for children.

Yes ☐ No ☐

☐ **Yes** ☐ **No**

2. Is the neonate of uncertain viability?

*If Yes,
Requirement #1:*

Yes ☐ No ☐

☐ **Yes** ☐ **No**

- Does the research hold out the prospect of enhancing the probability of survival to the point of viability, and is any risk the least possible for achieving that objective?

Yes ☐ No ☐

☐ **Yes** ☐ **No**

OR

- Is the purpose of the research the development of important biomedical knowledge which cannot be obtained by other means and will there be no added risk to the neonate?

Yes ☐ No ☐

☐ **Yes** ☐ **No**

Requirement #2:

- Has informed consent been obtained from either parent or either parent's legally authorized representative (if parents are unable)?

Yes ☐ No ☐

☐ **Yes** ☐ **No**

3. Is the neonate non-viable?

If yes,

Yes ☐ No ☐

☐ **Yes** ☐ **No**

- Will the vital functions of the infant not be artificially maintained?
- Will the research not terminate the heartbeat or respiration?
- Will there be no added risk to the neonate?
- Will the purpose of the research be the development of important biomedical knowledge that cannot be obtained by other means?
- Has the legally effective informed consent been obtained from both parents or, if one parent is unable to provide consent, from the other parent?

Yes ☐ No ☐

☐ **Yes** ☐ **No**

Yes ☐ No ☐

☐ **Yes** ☐ **No**

Yes ☐ No ☐

☐ **Yes** ☐ **No**

Yes ☐ No ☐

☐ **Yes** ☐ **No**

Yes ☐ No ☐

☐ **Yes** ☐ **No**

CPHS Use Only
Project #

Reviewer: _____

Date: _____

Rec: _____

To Rev: _____

From Rev: _____

**Reviewer
Concurs:**

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Project #

Reviewer:

Principal Investigator Signature: _____ Date: _____

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☐ **Approved** ☐ **Approval Deferred Pending Revisions (Provide Comments)** ☐ **Not Approved**

Comments:

Primary Reviewer Signature: _____ Date: _____